

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

Complete if Known

| | |
|----------------------|------------------------|
| Application Number | 09/975,253-Conf. #8837 |
| Filing Date | October 12, 2001 |
| First Named Inventor | Paul A. Moore |
| Examiner Name | S. L. Wegert |
| Art Unit | 1647 |
| Attorney Docket No. | PF196P1 |

TOTAL AMOUNT OF PAYMENT (\$) 1,330.00

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number

08-3425

Deposit Account Name

Human Genome Sciences, Inc.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code Fee (\$) Fee Code Fee (\$)

Fee Description

Fee Paid

| | | | | | |
|---------------------|--------|------|--------|--|----------|
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet. | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for <i>ex parte</i> reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |
| Other fee (specify) | 1454 | | | Acceptance of an unintentionally delayed claim for priority | 1,330.00 |

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 1,330.00

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Small Entity

Fee Code Fee (\$) Fee Code Fee (\$)

Fee Description

Fee Paid

| | | | | | |
|------|-----|------|-----|------------------------|--|
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |

SUBTOTAL (1) (\$) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | | | | | | | | |
|--------------------|----|---------|--|--------------|--|----------------|--|----------|------|
| Total Claims | 27 | -36** = | | Extra Claims | | Fee from below | | Fee Paid | 0.00 |
| Independent Claims | 2 | -3** = | | | | | | 0.00 | |
| Multiple Dependent | | | | | | | | | |

Large Entity Small Entity

Fee Code Fee (\$) Fee Code Fee (\$)

Fee Description

| | | | | | |
|------|-----|------|-----|--|--|
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 | |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 | |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid | |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent | |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent | |

SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Reissues, see above

SUBMITTED BY

Name (Print/Type) Mark J. Hyman

Registration No. (Attorney/Agent)

46,789

(Complete (if applicable))

Telephone (240) 314-1224

Signature

Date

July 26, 2004



DAC / IFW
A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Moore et al.

Docket No.: PF196P1

Application No.: 09/975,253

Confirmation No.: 8837

Filed: October 12, 2001

Art Unit: 1647

For: Methods and Composition for Treating and
Preventing Infection Using Human Interferon
Regulatory Factor 3

Examiner: S. L. Wegert

**PROVISIONAL ELECTION UNDER 37 C.F.R. § 1.143 WITH TRAVERSE AND
AMENDMENT UNDER 37 C.F.R. § 1.111**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed June 30, 2004, please consider the following amendments, traversal, provisional election, and remarks. Applicants respectfully request that the Examiner enter the following amendments prior to examination of the captioned application. Applicants submit concurrently herewith: (a) a Fee Transmittal Sheet with appropriate fee; (b) a Supplemental Application Data Sheet; and (c) a Petition to Accept Unintentionally Delayed Benefit Claim Under 37 C.F.R. §§ 1.78(a)(3) and/or (6).

Please amend the application as follows:

07/27/2004 ZJU HAR1 00000020 083425 09975253

01 FC:1454 1330.00 DA

In the Specification:

Please replace paragraph [0001] with the following rewritten paragraph:

[0001] This application claims benefit under 35 U.S.C. § 119(e) ~~based on~~ of U.S. Provisional Application No. 60/239,936, filed October 13, 2000; this application is also and is a continuation-in-part of U.S. Application No. 09/417,540, filed October 14, 1999 (now U.S. Patent No. 6,639,052, issued October 28, 2003), which is a divisional of, and claims benefit under 35 U.S.C. § 120 of U.S. Non-Provisional Application Serial No. 08/705,771, filed August 30, 1996 (now U.S. Patent U.S. Patent No. 6,054,289, issued April 25, 2000), which claims benefit under 35 U.S.C. § 119(e) based on of U.S. Provisional Application No. 60/002,993, filed August 30, 1995, each of which U.S. Application Nos. 60/239,936, 08/705,771, and 60/002,993 are hereby incorporated by reference in their entireties.

Amendments to the Claims:

The following listing of claims will replace all prior versions and listings of claims.

Listing of Claims

1. (original) An isolated polynucleotide comprising a nucleic acid sequence selected from the group consisting of:
 - (a) a polynucleotide encoding amino acids 1-427 of SEQ ID NO:2
 - (b) a polynucleotide encoding amino acids 1-407 of SEQ ID NO:2;
 - (c) a polynucleotide encoding amino acids 2-427 of SEQ ID NO:2;
 - (d) a polynucleotide encoding amino acids 198-381 of SEQ ID NO:2;
 - (e) a polynucleotide encoding amino acids 382-407 of SEQ ID NO:2;
 - (f) a polynucleotide encoding amino acids 408-427 of SEQ ID NO:2;
 - (g) a polynucleotide encoding amino acids 306-427 of SEQ ID NO:2;
 - (h) a polynucleotide encoding the amino acid sequence encoded by the cDNA contained in ATCC Deposit No. 97242;
 - (i) a polynucleotide encoding at least 30 contiguous amino acids of SEQ ID NO:2 or the cDNA clone contained in ATCC Deposit No. 97242;
 - (j) a polynucleotide encoding at least 50 contiguous amino acids of SEQ ID NO:2 or the cDNA clone contained in ATCC Deposit No. 97242;
 - (k) a polynucleotide of at least 30 contiguous nucleotides of SEQ ID NO:1 or the coding strand of the cDNA clone contained in ATCC Deposit No. 97242;
 - (l) a polynucleotide of at least 40 contiguous nucleotides of SEQ ID NO:1 or the coding strand of the cDNA clone contained in ATCC Deposit No. 97242;
 - (m) a polynucleotide of at least 50 contiguous nucleotides of SEQ ID NO:1 or the coding strand of the cDNA clone contained in ATCC Deposit No. 97242;
 - (n) a polynucleotide of at least 60 contiguous nucleotides of SEQ ID NO:1 or the coding strand of the cDNA clone contained in ATCC Deposit No. 97242; and
 - (o) the complement of (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), or (m).
2. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (a).
3. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (b).
4. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (c).

5. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (d).
6. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (e).
7. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (f).
8. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (g).
9. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (h).
10. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (i).
11. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (j).
12. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (k).
13. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (l).
14. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (m).
15. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (n).
16. (original) The isolated polynucleotide of claim 1, wherein said polynucleotide is (o).
17. (original) The isolated polynucleotide of claim 1 fused to a heterologous polynucleotide.
18. (original) The isolated polynucleotide of claim 17, wherein the heterologous polynucleotide encodes for a heterologous polypeptide.
19. (original) The isolated polynucleotide of claim 1, wherein the polynucleotide is double stranded.
20. (original) A recombinant vector comprising the polynucleotide of claim 1.
21. (original) The vector of claim 20 wherein the vector is a viral vector.
22. (original) The vector of claim 21 wherein the viral vector is a retroviral vector.
23. (original) A host cell comprising the polynucleotide of claim 1.

24. (original) A host cell comprising the polynucleotide of claim 1, wherein said polynucleotide is operatively associated with a heterologous regulatory sequence.
25. (original) An isolated polynucleotide that hybridizes to SEQ ID NO:1 or the cDNA clone contained in ATCC Deposit No. 97272, wherein said hybridization takes place under stringent hybridization conditions.
26. (original) A method of producing a protein comprising:
(a) culturing the host cell of claim 23 under conditions such that said protein is expressed; and
(b) recovering said protein.
27. (canceled)
28. (original) A method of gene therapy for preventing, treating, or ameliorating an infectious disease comprising administering to a mammal a polynucleotide of claim 1.
- 29-36. (canceled)

Remarks

Applicants have canceled claims 27 and 29-36 without prejudice or disclaimer. Applicants have also amended the benefit claim as discussed in the Petition for Acceptance of Unintentionally Delayed Benefit Claim submitted herewith, and updated the address of inventor Moore.

Claims 1-26 and 28 are pending.

The Restriction Requirement

Pursuant to the Office Action mailed June 30, 2004, the Examiner has required an election under 35 U.S.C. § 121 of one of Groups I to III. The Examiner contends that the inventions of the Groups are distinct, each from the other.

In order to be fully responsive, Applicants provisionally elect, *with traverse*, the subject matter of Group I, directed to, *inter alia*, polynucleotides, represented by original claims 1-26. Applicants point out that claims 27 and 29-36 have been canceled without prejudice or disclaimer.

With respect to the Examiner's restriction of groups directed to a nucleic acid sequence, antibodies recognizing such polypeptides, and methods of using the same, Applicants traverse. Even where patentably distinct inventions appear in a single application, restriction remains improper unless the examiner can show that the search and examination of these groups would entail a "serious burden". *See* M.P.E.P. § 803. In the present situation, although the Examiner has argued that Groups I-III are separately classified or represent divergent subject matter, Applicants nonetheless submit that, with respect to a given gene, a search of the claims of the groups directed to that gene would also provide useful information for the claims of the other groups directed to that gene. For example, in many if not most publications disclosing a gene, the authors also disclose the encoded protein, antibodies to the protein, and methods of using the same. Thus, since the searches for nucleic acids, antibodies to the proteins encoded thereby, and methods of using the same commonly overlap, Applicants respectfully disagree with the Examiner's assertion that the combined search and examination of such compositions and methods using the same would entail a serious burden, even assuming *arguendo* that all of the searches were not coextensive.

Accordingly, in view of M.P.E.P. § 803, claims directed to the Groups I to III should be searched and examined in the present application. Applicants therefore respectfully request that

the restriction requirement under 35 U.S.C. § 121 be reconsidered and withdrawn. Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

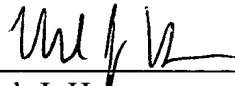
Conclusion

Entry of the above amendment is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: July 26, 2004

Respectfully submitted,

By 
Mark J. Hyman
Registration No.: 46,789
HUMAN GENOME SCIENCES, INC.
Intellectual Property Dept.
14200 Shady Grove Road
Rockville, Maryland 20850
(240) 314-1224

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Moore et al.

Docket No.: PF196P1

Application No.: 09/975,253

Confirmation No.: 8837

Filed: October 12, 2001

Art Unit: 1647

For: Methods and Composition for Treating and
Preventing Infection Using Human Interferon
Regulatory Factor 3

Examiner: S. L. Wegert

**PETITION TO ACCEPT UNINTENTIONALLY DELAYED BENEFIT CLAIM
UNDER 37 C.F.R. §§ 1.78(a)(3) AND/OR (6)**

MS Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The instant application directly claims benefit under 35 U.S.C. § 120 of U.S. App. No. 08/705,771, and through that application indirectly claims benefit under 35 U.S.C. § 119(e) of U.S. Provisional App. No. 60/002,993.¹ However, it has come to the attention of the undersigned that this application unintentionally omits a benefit claim under 35 U.S.C. § 120 to U.S. App. No. 09/417,540, which is a divisional application of the '771 application. As the instant application was copending with the '540 application, but not the '771 application (which issued April 25, 2000), correction of this unintentional omission is necessary to retain the benefit of the filing date of the '771 and '993 applications. Thus, Applicants hereby petition for acceptance of the unintentionally delayed benefit claims.

In support of this request, Applicants note the following:

1. A proper reference to the prior applications as required by 35 U.S.C. §§ 119(e) and 120, and 37 C.F.R. §§ 1.78(a)(2) and (5), is contained in both the Provisional Election Under 37 C.F.R. § 1.143 with Traverse and Amendment Under 37 C.F.R. § 1.111 and the Supplemental Application Data Sheet submitted herewith.

¹ This application also directly claims benefit under 35 U.S.C. § 119(e) of U.S. Provisional App. No. 60/239,936. This benefit claim was properly made and is not affected by the error discussed herein.

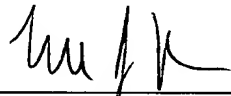
2. The surcharge set forth in 37 C.F.R. § 1.17(t) has been authorized to be paid from Deposit Account No. 08-3425, as itemized on the enclosed Fee Transmittal Sheet.
3. The undersigned hereby states that the entire delay between the date the benefit claim was due under 37 C.F.R. §§ (a)(2)(ii) and (a)(5)(ii) and the date the claim was filed was unintentional.

Accordingly, as the above submissions fully satisfy the requirements of 37 C.F.R. §§ 1.78(a)(3) and (a)(6), Applicants respectfully request that the instant petition be granted, and that the unintentionally delayed benefit claim submitted herewith be accepted and entered in the instant application.

If any further action by Applicants is required, please call the undersigned at the phone number provided below. If there are any additional fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425.

Dated: July 26, 2004

Respectfully submitted,

By  _____

Mark J. Hyman

Registration No.: 46,789

HUMAN GENOME SCIENCES, INC.

Intellectual Property Dept.

14200 Shady Grove Road

Rockville, Maryland 20850

(240) 314-1224



Supplemental Application Data Sheet

Application Information

| | |
|----------------------------------|---|
| Application number:: | 09/975,253 |
| Filing Date:: | 10/12/01 |
| Application Type:: | Regular |
| Subject Matter:: | Utility |
| CD-ROM or CD-R?:: | None |
| Sequence submission?:: | Paper |
| Computer Readable Form (CRF)?:: | Yes |
| Number of copies of CRF:: | 1 |
| Title:: | Methods and Compositions for Treating and Preventing Infection Using Human Interferon Regulatory Factor 3 |
| Attorney Docket Number:: | PF196P1 |
| Request for Early Publication?:: | No |
| Request for Non-Publication?:: | No |
| Total Drawing Sheets:: | 4 |
| Small Entity?:: | No |
| Petition included?:: | No |
| Secrecy Order in Parent Appl.?:: | No |

Applicant Information

| | |
|----------------------------------|-----------------------|
| Applicant Authority Type:: | Inventor |
| Primary Citizenship Country:: | United Kingdom |
| Status:: | Full Capacity |
| Given Name:: | Paul |
| Middle Name:: | A. |
| Family Name:: | Moore |
| City of Residence:: | <u>North Bethesda</u> |
| State or Province of Residence:: | MD |
| Country of Residence:: | US |

Street of mailing address:: 7013 Old Gate Road
City of mailing address:: North Bethesda
State or Province of mailing address:: MD
Postal or Zip Code of mailing address:: 20852

Applicant Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Full Capacity
Given Name:: Paula
Family Name:: Pitha-Rowe
City of Residence:: Baltimore
State or Province of Residence:: MD
Country of Residence:: US
Street of mailing address:: 4000 N. Charles Street
Unit 1612
City of mailing address:: Baltimore
State or Province of mailing address:: MD
Postal or Zip Code of mailing address:: 21218

Correspondence Information

Correspondence Customer Number:: 22195

Representative Information

Representative Customer Number:: 22195

Domestic Priority Information

| Application:: | Continuity Type:: | Parent Application:: | Parent Filing Date:: |
|-------------------|---|--|--|
| This Application | An application claiming the benefit under 35 USC 119(e) | 60/239,936 | 10/13/00 |
| This Application | Continuation-in-part of | 08/705,771 <u>09/417,540</u> | 08/30/96 <u>10/14/99</u> |
| <u>09/417,540</u> | <u>Division of</u> | <u>08/705,771</u> | <u>08/30/96</u> |
| 08/705,771 | An application claiming the benefit under 35 USC 119(e) | 60/002,993 | 08/30/95 |

Assignee Information

Assignee name:: Human Genome Sciences, Inc.
Street of mailing address:: 14200 Shady Grove Road
City of mailing address:: Rockville
State or Province of mailing address:: MD
Postal or Zip Code of mailing address:: 20850

Assignee name:: Johns Hopkins University
Street of mailing address:: 3400 N. Charles Street
City of mailing address:: Baltimore
State or Province of mailing address:: MD
Postal or Zip Code of mailing address:: 21218